

ARTICLE 20:51

PHARMACISTS

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CHAPTER 20:51:30

TELEPHARMACY

Section

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20:51:30:01. Definitions. Terms used in this chapter mean:

- (1) “Automated mechanical distribution device,” as defined in § 20:51:17:01;
- (2) “Central pharmacy,” as defined in SDCL 36-11-71(1);
- (3) “Remote pharmacy,” as defined in SDCL 36-11-71(2);
- (4) “Telepharmacy practice,” as defined in SDCL 36-11-71(3);

Source:

General Authority: SDCL 36-11-11(1), 36-11-71(2),(3).

Law Implemented: SDCL 36-11-11(1),(4),(5), 36-11-71.

20:51:30:02. Application for remote pharmacy site. No remote pharmacy may be established, operated, or maintained unless the board issues a license. An application for licensure to establish, operate, or maintain a remote pharmacy shall be made on a form provided by the board. A set of blueprints and documentation showing that all requirements of this chapter have been met shall be provided to the board with the application for licensure. The initial license fee for a remote pharmacy is \$200. The board shall approve or disapprove an application within 60 days of receipt.

The applicant shall demonstrate to the board that there is limited or no access to pharmacy services in the community. The board at its discretion will consider the needs of the community when issuing a license for a remote pharmacy.

Source:

General Authority: SDCL 36-11-11(1), 36-11-72(1).

Law Implemented: SDCL 36-11-72(1).

20:51:30:03. Ownership or control by pharmacist required. The board may not issue a permit to conduct a remote pharmacy to any pharmacist applicant unless such pharmacist applicant is an owner, or part owner, of the place of business from which the pharmacist will practice telepharmacy, or unless the non-pharmacist owner of the place of business from which the pharmacist will practice telepharmacy files an affidavit on a form

prescribed by the board delegating full and complete authority to the pharmacist applicant to be in active management of the place of business for the license year ending June 30.

Source:

General Authority: SDCL 36-11-11(1), 36-11-72(1).

Law Implemented: SDCL 36-11-34, 36-11-72.

20:51:30:04. Board inspection. No remote pharmacy may provide pharmacy services until the board has inspected the remote pharmacy for minimum equipment, size, security, and sanitation standards as set forth in § 20:51:07:01 and found the remote pharmacy to be in compliance with such standards.

Source:

General Authority: SDCL 36-11-11, 36-11-72.

Law Implemented: SDCL 36-11-71, 36-11-72.

20:51:30:05. License renewal. A remote pharmacy license expires on June 30 of each year and may be renewed annually by filing an application provided by the board. The renewal fee is \$200.

Source:

General Authority: SDCL 36-11-72(1).

Law Implemented: SDCL 36-11-72(1).

20:51:30:06. License required. Any pharmacy licensed by the Board may operate a remote pharmacy in South Dakota. The remote pharmacy is considered an extension of the central pharmacy. However, the remote pharmacy must have its own license as a pharmacy.

Source:

General Authority: SDCL 36-11-19(3), 36-11-72(1).

Law Implemented: SDCL 36-11-19(3), 36-11-72(1).

20:51:30:07. Audiovisual link. There must be a continuous, two-way audiovisual link between the central pharmacy and the remote pharmacy. The transmission of information through the computer link must make information available to the central pharmacy and the remote pharmacy simultaneously. The video camera used for the certification of prescriptions must be of sufficient quality and resolution so that the certifying pharmacist can visually

identify the markings on tablets and capsules. Unless the camera used to certify prescriptions can also be used to monitor activities in other parts of the remote site, a second camera is required. A security camera trained on the entire dispensing area is sufficient to meet the requirement.

Source:

General Authority: SDCL 36-11-11(1), 36-11-72(2)..

Law Implemented: SDCL 36-11-72(2).

20:51:30:08. Remote pharmacy identification sign. Each remote site shall display a sign easily viewable by customers stating “This business is a remote pharmacy, supervised by a pharmacist located at (*insert name of pharmacy and address*)”.

Source:

General Authority: SDCL 36-11-11(1), 36-11-72(2,5).

Law Implemented: SDCL 36-11-72(2,5).

20:51:30:09. Restricted area posted. The remote pharmacy dispensing area shall be posted as a restricted area. Only pharmacy technicians or pharmacy interns employed directly and involved in processing prescriptions are permitted in the dispensing area. There must be restricted access to the restricted area. The security system at the remote pharmacy must allow for tracking of each entry into the pharmacy. The pharmacist-in-charge shall review the log of entries at least weekly.

Source:

General Authority: SDCL 36-11-11(1), 36-11-72(2,5).

Law Implemented: SDCL 36-11-72(2,5).

20:51:30:10. Toll-free telephone number. The remote pharmacy shall provide a toll-free telephone number that patients and prescribers may use to contact the central pharmacy. The telephone number shall be printed on the label of each prescription container.

Source:

General Authority: SDCL 36-11-11(1), 36-11-72(2,5).

Law Implemented: SDCL 36-11-72(2,5).

20:51:30:11. Pharmacist staffing requirements. Any pharmacist performing services in support of a remote pharmacy, whether those services are performed at the central pharmacy or the remote pharmacy, must be licensed by the board. A copy of the pharmacist's license must be posted in any remote pharmacy to which the pharmacist provides services.

Source:

General Authority: SDCL 36-11-11, 36-11-13, 36-11-72(3).

Law Implemented: SDCL 36-11-72(3).

20:51:30:12. Technician and intern staffing requirements. Each remote pharmacy must be staffed with South Dakota registered pharmacy technicians or interns. A pharmacy technician working at a remote pharmacy shall have a minimum of 2000 hours of experience as a registered pharmacy technician in accordance with § 20:51:29 and shall be certified through one of the certification programs recognized by the board. An intern working at a remote pharmacy shall have a minimum of 500 hours of experience as a registered pharmacy intern in accordance with § 20:51:02.

Source:

General Authority: SDCL 36-11-11(1,14,), 36-11-72(3).

Law Implemented: SDCL 36-11-72(3).

20:51:30:13. Pharmacist-to-technician ratio. The pharmacist on duty at a central pharmacy may supervise no more than the number of technicians allowed in accordance with §20:51:29:19. The total number of allowed technicians may be divided between the central pharmacy and the remote pharmacy in any manner. However, each remote pharmacy must have at least one pharmacy technician or pharmacy intern on duty when it is open.

Source:

General Authority: SDCL 36-11-11(1,14), 36-11-72(3).

Law Implemented: SDCL 36-11-72(3).

20:51:30:14. Prescription workload. Any central pharmacy providing telepharmacy services shall provide pharmacist staffing to meet the prescription workload of both the central pharmacy and the remote pharmacy.

Source:

General Authority: SDCL 36-11-11, 36-11-72(3).

Law Implemented: SDCL 36-11-72(3).

20:51:30:15. Requirements for prescription orders. Only a registered pharmacist may take a verbal prescription order. A pharmacy technician at the remote pharmacy may not accept verbal orders for new prescriptions, but may accept written orders. A written order for a new prescription may be entered at the central pharmacy or the remote pharmacy. The pharmacist must approve or override all drug utilization review alerts.

Source:

General Authority: SDCL 36-11-11(1), 36-11-72(5).

Law Implemented: SDCL 36-11-72(5).

20:51:30:16. Requirements for operation. The following requirements must be adhered to when operating a remote pharmacy:

(1) The remote pharmacy may only be open if computer link, video link, and audio link with the central pharmacy are functioning properly. If any link is not functioning properly, the remote pharmacy must be closed unless a pharmacist is working at the remote pharmacy;

(2) No remote pharmacy may be open when the central pharmacy is closed, unless a licensed pharmacist is working at the remote pharmacy;

(3) Any prescription filled at the remote pharmacy must be profiled, reviewed, and interpreted by a pharmacist at the central pharmacy before the prescription is dispensed;

(4) Any remotely dispensed prescriptions must have a label properly prepared in accordance with § 20:51:05:21 attached to the final drug container before the pharmacist certifies the dispensing process. This prescription certification process must be done in real time. All prescription certification must be documented in the computer record. The computer must be capable of carrying the initials of the technician preparing the prescription and the pharmacist verifying the prescription. Verification is required for both new prescriptions and refills;

(5) When the patient receives a prescription, the pharmacist must use audiovisual communication to counsel the patient regarding use of the prescription being dispensed. Counseling is required only for new prescriptions. The pharmacist must meet the counseling standards in accordance with § 20:51:25:04;

(6) The remote pharmacy must maintain a log, signed by the patient, that documents a patient's refusal for counseling by the pharmacist.

Source:

General Authority: SDCL 36-11-11(1), 36-11-72(2,3,4,5).

Law Implemented: SDCL 36-11-72(2,3,4,5).

20:51:30:17. Routine quality assurance required. The pharmacist-in-charge must develop policies and procedures to ensure the safe and effective distribution of pharmaceutical products and delivery of required pharmaceutical care. Policy and procedures must be reviewed annually and be signed by both the technician at the telepharmacy and the pharmacist-in-charge at the central pharmacy.

All revisions to policies and procedures made after initial board approval shall be resubmitted to the board for approval.

The pharmacist-in-charge must adhere to the following procedures:

(1) Inspect the remote pharmacy at weekly intervals or more if deemed necessary. Inspection must be documented and kept on file at the remote pharmacy and available upon request by the board;

(2) Implement and conduct a quality assurance plan that provides for on-going review of dispensing errors, with appropriate action taken, if necessary, to assure patient safety;

(3) Verify controlled substance prescriptions for both accuracy and legitimacy of the original prescription by the pharmacist-in-charge or a designated pharmacist during weekly inspection visits;

(4) Maintain records of all controlled substances stocked by the remote pharmacy through a daily perpetual inventory. Controlled substance perpetual inventory records must be

available for inspection by the board's inspectors. A remote pharmacy stocking controlled drugs must be registered by the Drug Enforcement Administration and South Dakota Department of Health:

(5) Conduct an inventory of all controlled substances at least monthly to verify accuracy.

Source:

General Authority: SDCL 36-11-11(1) and 36-11-72(4,5).

Law Implemented: SDCL 36-11-72(4,5).

20:51:30:18. Use of automated mechanical dispensing device. If the remote pharmacy uses an automated mechanical dispensing device, the stocking and loading of this device must either be checked by a pharmacist, prior to use, or employ a secure bar coding system or its equivalent. Policies and procedures consistent with § 20:51:17:02 regarding the operation of the automated mechanical distribution system must be developed and submitted to the board for consideration. After approval, these policies and procedures must be available at both the central pharmacy and the remote pharmacy.

Source:

General Authority: SDCL 36-11-11(1,6), 36-11-72(6).

Law Implemented: SDCL 36-11-11(6), 36-11-72(6).